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1 of 3
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7/11/02

IN THE UNITED STATES PATENT OFFICE

Inventor: W. Roy KNOWLES, M.D.
Filing Date: 19 July 2000
Ser. No.: 09/619,142
Examiner: Vickie KIM
Art Unit: 1614

Honorable Commissioner of Patents
Box Appeal Brief
Washington, DC 20231
BY EXPRESS MAIL

APPEAL BRIEF

This APPEAL BRIEF is submitted pursuant to the accompanying NOTICE OF APPEAL. This is a Special Case subject to an approved PETITION TO MAKE SPECIAL.

I. REAL PARTY IN INTEREST

The real party in interest is the applicant inventor.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals nor interferences which will directly affect nor be directly affected by nor have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

Claims 1-5, 7-16 and 18-22 stand four times rejected.

IV. STATUS OF AMENDMENTS

There are no pending Amendments.

V. SUMMARY OF INVENTION

A. Overview

The invention relates to maintaining healthy hair and preventing abnormal hair loss, by using *minoxidil* together with *a skin penetration enhancer* and a *testosterone blocker* or *inhibitor*.

B. The Art and Its Shortcomings

The background art has been amply explored in the five OFFICE ACTIONS issued in this case.[1]

1. Minoxidil

Minoxidil in the systemic blood circulation is a potent anti-hypertensive cardiovascular drug. The art cited by the Examiner teaches this. *See, e.g.*, Bradbury, U.S. 6,124,362 at col. 1, lines 28-29. Minoxidil over dosage may create cardiac arrhythmia. *See, e.g.*, Hoke, U.S. 5,994,319 at col. 5, lines 4-6 (systemic administration of finasteride creates unwanted side effects). Minoxidil is used topically as an anti-alopecia agent (*e.g.*, ROGAINE®). Topical minoxidil is not very effective against hair loss. The art cited by the Examiner uniformly teaches this. *E.g.*, Hoke at col. 3 lines 4-11; Bradbury at col. 1 lines 31-33; Bazzano, U.S. 6,183,817 at col. 3 lines 53-56, col. 5 lines 17-42, and col. 4 lines 49-54, 63-65; Partain, U.S. 4,946,870 at col. 13, line 59 to col. 14, line 2.

The Examiner's references also teach that topical use of minoxidil with a skin penetrating agent would load the drug into the systemic blood circulation. *E.g.*, Rajadhyaksha, U.S. 5,482,965 at col. 3 line 53-60, col. 7 line 40-57, col. 10 line 11-14, col. 18 line 1-28, col. 18 line 55 to col. 19 line 12, Example 32; Knowles, W.R., SUPPLEMENTAL DECLARATION at ¶¶ 7-10 (25 April 2001). The Examiner does not dispute that this risks precipitating cardiac side effects. OFFICE ACTION (27 Mar. 01). The examiner concedes that such risk is unacceptable for cosmetic use for hair loss. *Id.* Thus, minoxidil sold for hair loss has never included penetration enhancer. SPECIFICATION at 2-7; Knowles, W.R., RULE 132 DECLARATION at ¶ 7 (5 Feb. 2001).

2. Testosterone Blocker / Inhibitor

Testosterone blockers and inhibitors are known in the art. Progesterone, for example, is a birth control drug. Its systemic side effects include carcinogenicity, decreased libido, feminization, and impotency. Hoke at col. 4 line 22-24. It also "systemically disrupts the

[1] This case has an exceptionally well-developed factual record, which includes, *inter alia*, the following U.S. patents: Bazzano, 6,183,817; Bonte, 5,723,149; Bradbury, 6,124,362; Bromberg, 5,939,485; Buck, 5,609,858; Buck, 5,512,275; Casero, 5,340,579; Catz, WO/93/088__; Chidsey, 4,139,619; Chizick, 5,972,345; Crandall, 6,333,067; Diani, 5,578,599; Gibson, 5,015,470; Grollier, 5,192,534; Hachiman, JP-246836; Hoke, 5,994,319; Kincl, 9 J.Steroid Biochem. 83; Kita, 6,162,801; Liao, 5,422,371; Liao, 5,605,929; Lishko, 5,753,263; Messenger, 6,020,327; Mikulak, 50 J.Pharm Pharmacol. 153; Orentreich, 5,053,403; Patel, 4,663,970; Rajadhyaksha, 5,482,955; Roentsch, 5,654,337; Tien, 5,574,011; Wong, 6,824,072.

menstrual cycle in women." Orentreich, U.S. 5,053,403 at 7. The Examiner concedes that these adverse side effects are "well documented." OFFICE ACTION at 5 (24 Oct. 2000).

Progesterone has been disclosed topically for hair loss. Orentreich, U.S. 5,053,403 at 7. Such teaching, however, due to concerns over potential systemic side effects, teaches away from including skin penetration enhancer with progesterone. Id. at col. 1 lines 45-52. Similarly, finasteride ("an effective inhibitor of the enzyme 5α-reductase") is known in the art to not be appropriate for use with penetration enhancer. Hoke at col. 4 line 18-24, col. 5 line 4-6.

The foregoing is expressly taught by the Examiner's own references, and is undisputed by the Examiner. *See* OFFICE ACTION at ¶ 1 (24 April 2002) (withdrawing rejections over Hoke, Orentreich, Bradbury, Bazzano, Rajadhyaksha).

C. Dr. Knowles' Counter-Intuitive Solution

Dr. Knowles has turned this conventional wisdom on its head. He has found that, contrary to the teachings of the art, penetration enhancer can safely be used with minoxidil and a testosterone blocker or inhibitor - **if** used properly. SPECIFICATION at 8-9. He tested his invention in rigorous, confidential clinical trials. His invention has been proven **ten times more effective** over prior art preparations, with **qualitatively better results**, with none of the **adverse side effects** feared in the prior art. SPECIFICATION at 8, 12-14; Knowles, W.R., RULE 131 DECLARATION (5 Feb. 2001) Knowles, W.R., RULE 132 DECLARATION (5 Feb. 2001).

The claims are drawn to a combination of minoxidil and a 5α-reductase inhibitor[2] and a skin-penetration enhancer. Claims 1, 3 and 4 read (emphasis added):

1. A composition of matter intended for topical use in preventing or treating alopecia, or maintaining healthy hair, said composition of matter comprising:
   a) an active compound selected from the group consisting of: a pharmaceutically or cosmetically effective topical amount of a 5α-reductase inhibitor and minoxidil, and
   b) a non-retinoid penetration enhancer, said penetration enhancer present *in a concentration sufficient to aid said active compound in penetrating the skin surface to a depth of approximately the depth of hair bulbs.*

[2] The Examiner prefers to use the term "5α-reductase inhibitor" as a substitute for Applicant's term "testosterone blocker." *E.g.*, OFFICE ACTION at 7 (28 Sept. 2001). Applicant has amended the claims accordingly. AMENDMENT pg. 2, lines 14-19 (10 Jan. 2002).

3. The composition of claim 1, wherein said active compound comprises minoxidil.

4. The composition of claim 3, further comprising a 5α-reductase inhibitor.

Claim 4 thus requires minoxidil + 5α-reductase inhibitor + penetration enhancer.

D. Conclusion

The examiner concedes that the aforementioned references lack certain claim limitations. The examiner, however, now relies on new references. The examiner concedes, however, that the same claim limitations are lacking in the new references as well. Further, Applicant has sworn behind the newly raised rejections.

Because the examiner concedes that the new references lack these claim limitations, and because the Applicant has sworn behind the new references, the rejections *must* be withdrawn as a matter of law.

E. Issues Presented

Whether Applicant has sworn behind the § 102(e) rejection over Crandall?

Whether Applicant has sworn behind the § 102(e) rejection over Roentsch?

Whether Roentsch teaches penetration enhancer "*penetrating the skin surface to a depth of approximately the depth of hair bulbs*"?

Whether the examiner is collaterally estopped from further contesting the issue of whether the claims can be anticipated by a reference which does not teach "penetration to a depth of approximately the depth of hair bulbs"?

F. References

The following references are enclosed (handwritten notations are the examiner's):

1. Bazzano

Bazzano, United States Letters Patent No. 5,183,817, claims using retinoid compounds for hair growth. Bazzano says that minoxidil *does not work* for hair loss.

2. Bradbury

Bradbury, United States Letters Patent No. 6,124,362, teaches the cosmetic use of lupine triperpine compounds for hair-growth. Bradbury notes that minoxidil is "a potent antihypertensive," and that "not all people respond to minoxidil and the efficacy level is limited in those individuals who do." Col. 1, lines 25-34.

3. Crandall

Crandall discloses "a topical and oral treatment of topical treatment of hair loss." Id. at Abstract.

4. Grollier

Grollier teaches a "composition for inducing and stimulating hair growth or retarding its loss, based on pyrimidine derivatives and sunscreens." Id. at Title.

5. Hoke

Hoke, United States Letters Patent No. 5,994,319, teaches that progesterone and minoxidil are unacceptable for hair loss (progesterone has severe adverse systemic effects, col. 4 lines 18-23; minoxidil has "potent" cardiovascular side effects and doesn't work well, col. 3 lines 4-14). Hoke instead advocates and claims anti-sense nucleotides.

6. Orentreich

Orentreich, United States Letters Patent No. 5,053,403, mentions the topical use for hair loss of progesterone. Orentreich, however, admonishes that progesterone has systemic side effects so serious that *it should not be systemically administered* for hair loss. Id. at col. 1 lines 45-51 ("The serious side effects (such as decreased libido) produced by the systemic administration of antiandrogens precludes the systemic use of these drugs for the treatment of the above skin disorders. For example, progesterone is a highly active 5*a* reductase enzyme inhibitor, but systematically disturbs the menstrual cycle in women"). Orentreich further cautions that progesterone must be combined with a "blocking agent" to prevent such systemic side effects.

7. Partain

Partain, United States Letters Patent No. 4,946,870, teaches the topical use of chitosan derivatives as skin "humectants" (agents that keep the skin wet). Partain notes that "moisturization of the skin and mucous membranes enhances absorption and permeation of most pharmaceutical and therapeutic actives." Id. at col. 3, line 53-57. Partian thus teaches an anti-alopecia lotion of chitosinium niacinate and nicotinic acid, an "anti-alopecia agent." Id. at col. 13, lines 59 - col. 14, line 2. Partain suggests further including minoxidil. Id. Partain, however, recognizes that minoxidil is not aided by humectants because minoxidil has limited percutaneous

absorption (perhaps because it is not soluble in lipophyllic skin tissue, SPECIFICATION at 5), acknowledges that minoxidil does not work if used without nicotinic acid. Id.

8. Rajadhyaksha

Rajadhyaksha, United States Letters Patent No. 5,482,965, teaches improved trans-dermal drug delivery agents. Rajadhyaksha teaches that his compounds effectively deliver drugs into the systemic blood circulation. Id. at col. 2 line 16-19. The compounds pass "through the skin and the systemic circulation" to the liver and yield nontoxic liver metabolites. Id.

9. Roentsch

Roentsch discloses and claims a new trans-dermal drug delivery skin-penetration enhancer, and its use for the trans-dermal delivery of angina, analgesic and anti-neoplastic drugs. Id. at Abstract.

G. Separately-Patentable Claims

The following groups of claims are separately patentable:

Group 1 (Gibson § 102(b)): 1, 3, 12, 14.

Group 2 (Crandall § 102(e)) : 5, 7-10, 16, 18-21.

Group 3 (Roentsch § 102(e)) : 2, 4, 11, 13, 15, 22.

Group 4 (Roentsch § 103) : 11, 22.

We will now review each group in turn.

VI. ARGUMENT

OK

A. Group 1 - § 102(b) over Gibson

The Group 1 claims (1, 3, 12, 14) stand newly-rejected as anticipated under 35 U.S.C. § 102(b) by Gibson *et al.* Applicant does not contest this rejection.[3]

B. Group 2 - § 102(e) or § 103 over Crandall

The Group 2 claims stand rejected as anticipated under 35 USC § 102(e) or obvious under 35 USC § 103 in view of Crandall *et al.* These rejections must be reversed as a matter of law.

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[3] *N.b.*: The Group 1 claims also stand rejected as anticipated under 35 U.S.C. § 102(e) by Roentsch *et al.* The § 102(e) rejection must be withdrawn, however, because Applicant antedates Roentsch. *See infra*.

The application is examined under the pre-AIPA version of § 102(e):

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent.

35 U.S.C.A. § 102(e) (2000) (emphasis added). provisional → Oct 19 1995.

Here, Crandall was filed in the United States on 16 July 1998. Crandall was thus filed in the United States after the invention of the claimed invention by the Applicant. Knowles, W.R., RULE 1.131 DECLARATION at ¶ 2 (5 Feb. 2001) ("Not later than April 14, 1996, I conceived of an invention having each of the elements of my pending patent claims."); Knowles, W.R., RULE 1.131 DECLARATION at ¶ 2 (9 Jan. 2002) (same).

Any alleged deficiency in these Declarations must have been pointed out in the first office action issued after the declaration is filed. M.P.E.P. § 602.03 (Aug. 2001) ("In *the first* Office action the examiner *must* point out *every* deficiency in a declaration or oath and require that the same be remedied.") (emphasis added). Here, the first office action following the 5 Feb. 01 DECLARATION acknowledged receipt of the declaration, but did not point out any deficiency in it.[4] OFFICE ACTION at ¶ 1 (27 Mar. 01). Similarly, the first office action following the 9 Jan. 02 DECLARATION acknowledged receipt of the declaration, but did not point out any deficiency in it. OFFICE ACTION at ¶ 1 (9 May 02). Thus, under established PTO protocol, the Examiner has accepted these Declarations.

Because Crandall was filed in the United States after the invention of the claimed invention by the applicant, Applicant antedates Crandall. Thus, all rejections based on Crandall must be withdrawn as a matter of law. This holds for rejections under § 102(e) based on Crandall alone, as well as for all rejections under § 103 for any combination of references using Crandall. M.P.E.P. § 715.02 at pg. 700-205 (Aug. 2001) (swearing behind any single reference in a combination of references antedates the combination).

Because Applicant has sworn behind Crandall, Applicant has overcome the only two grounds for rejecting the Group 2 claims. The claims thus must be allowed as a matter of law. There is no discretion on the part of the Patent Office in allowing these claims; because the

[4] To the contrary, the Examiner relied on the DECLARATION. Id. at ¶ 2.

statutory requirements have been met, the claims *must* issue. Markman v. Westview Instr., Inc., 52 F.3d 967 (Fed. Cir. 1995) (*en banc*) (*citing* 35 U.S.C. § 151).

C. Group 3

The Group 3 claims stand rejected under 35 USC § 102(e) over Roentsch. OFFICE ACTION pg. 4 ¶ 6 (9 May 2002). This rejection must be withdrawn because Applicant antedates Roentsch. Furthermore, the examiner concedes that Roentsch does not teach all claim elements, and is collaterally estopped from arguing otherwise.

1. Applicant antedates the Reference

The Application was filed 19 July 2000. Thus, the application is examined under the pre-AIPA version of § 102(e):

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent.

35 U.S.C.A. § 102(e) (2000) (emphasis added).

Here, Roentsch was filed in the United States on 24 March 1995. Roentsch was thus filed in the United States after the invention of the claimed invention by the Applicant. Knowles, W.R., DECLARATION at ¶ 2 (24 June 2002).[5] Because Roentsch was filed in the United States after the invention of the claimed invention by the applicant, Roentsch cannot anticipate the claims under § 102(e) as a matter of law. Because this overcomes the only grounds for rejection, the statutory requirements have been met, and the Group 3 claims *must* issue. Markman v. Westview Instr., Inc., 52 F.3d 967 (Fed. Cir. 1995) (*en banc*) (*citing* 35 U.S.C. 151).

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[5] To be admitted, this Declaration should be timely filed. M.P.E.P. § 715.09 (Aug. 2001). "Timely filed" means filed with a first reply after final rejection, for the purpose of overcoming a new ground of rejection. Id. at § 715.09(C)(1). Here, Roentsch is a ground of rejection newly raised in the last Office Action. The declaration has been filed with the first reply after this rejection, and is filed for the purpose of overcoming it. Thus, according to established Patent Office procedure, the Declaration is timely filed.

Further, the Declaration is necessary. To respond to a new ground for rejection made final, Applicant can offer an affidavit to preclude re-opening prosecution. In re Doebel, 461 F.2d 823, 825; In re Hyson, 453 F.2d 764, 766 n.2; In re Cavrich, 451 F.2d 1091, 1093; In re Ahlert, 424 F.2d 1088, 1092; In re Jacobson, 407 F.2d 890, 893-94. In the immediate case, Examiner has previously refused to proceed with an appeal and re-opened prosecution over Applicant's objection. OFFICE ACTION at 2, ¶ 4 (28 Sept. 2001). *Five* Office Actions have already been issued in this case. The case therefore will not benefit from further factual development. Applicant would like to preclude Examiner from reopening prosecution again. Thus, the Declaration is necessary.

2. The reference does not teach penetration enhancer "penetrating the skin surface to a depth of approximately the depth of hair bulbs"

The pending claims require penetration enhancer "*...penetrating the skin surface to a depth of approximately the depth of hair bulbs.*" SPECIFICATION at claim 1 ¶ (b). Roentsch does not teach this.

To the contrary, Roentsch teaches delivering drugs **completely through the skin** into the systemic bloodstream. The Examiner agrees that Hoke, Orentreich, Bradbury, Bazzano and Rajadhyaksha each teach transdermal delivery of drugs completely through the skin and into the systemic blood circulation. *See* OFFICE ACTION at ¶ 1 (24 April 2002) (withdrawing rejections over Hoke, Orentreich, Bradbury, Bazzano, Rajadhyaksha). Roentsch teaches no more.

Roentsch discloses and claims an improved skin penetration agent. Roentsch teaches that his new transdermal drug delivery compound delivers drugs **completely through the skin** and into the systemic bloodstream. Roentsch summarizes:

> This invention relates to a composition useful in the delivery of pharmaceutically active agents through the skin. In one embodiment of the invention, the composition is formulated with a non-steroidal anti-inflammatory agent, such as ibuprofen or ketoprofen; a muscle relaxant, such as cyclobenzaprine; or other active ingredient. Such formulation is rapidly absorbed through the skin to provide local relief from pain, muscle spasms, or other pathological condition. In another embodiment of the invention, the composition is formulated with an antineoplastic or other pharmaceutically-active agent. Such formulation is rapidly absorbed through the skin to provide local delivery to subcutaneous tumors and other subdermal sites in need of treatment.

Id. at col. 1, line 7-21. Thus, the reference teaches drug delivery completely through the skin, into muscle tissue, subcutaneous tumors, and to other subdermal sites. *Id.* at col. 2, line 65-67. As examples, Roentsch provides for the systemic administration of the anti-angina drug nifedipine (*id.* at col. 3, line 59-60 and Example 7), the anti-asthma drug aminophylline (*id.* at col. 3, line 59-60 and Example 13), and various pain relievers. Roentsch specifically teaches that his compound is useful for drugs which are useful at all only when systemically administered. *E.g., id.* at col. 3, line 59-60 and col. 4, line 55-57. Knowles, W.R., DECLARATION at ¶¶ 36-45 (24 June 2002).

Roentsch also says, "compositions comprising a mixture of minoxidil and a testosterone 5α-reductase inhibitor would be very beneficial for inducing hair growth." Id. at col. 6 line 15-16. Roentsch, however, acknowledges that his skin penetration enhancer has "very good skin penetration," id., and thus cautions that his compound be used only "as long as local reactions or toxicity due to the active ingredient do not become a problem," id. at lines 36-40. Roentsch thus does not suggest nor enable a way to avoid systemic toxicity and side effects due to systemic administration of minoxidil or 5α-reductase inhibitor. To the contrary, by teaching a highly effective skin penetrant, Roentsch fails to enable one of skill to practice the claim limitation, "*penetrating the skin surface to a depth of approximately the depth of hair bulbs.*" Knowles, W.R., DECLARATION at ¶¶ 36-45 (24 June 2002).

Significantly, the Examiner agrees with this, conceding that Roentsch teaches transdermal drug delivery completely "through the skin." OFFICE ACTION at 4 (24 April 2002) ("penetration enhancer (i.e. speed-gel) is useful in the delivery of pharmaceutically active agents through the skin to provide local relief by local delivery to targeted active site of action (e.g. subdermal sites"). The Examiner does not even allege Roentsch teaches delivery to "a depth of approximately the depth of hair bulbs."

3. Judicial Notice of this fact is Illegal

The Examiner, however, takes judicial notice that "One of skilled artisan would have envisaged the enhanced delivery of active compound to the hair bulbs . . . via improved penetration thru skin layers by penetration enhancer." OFFICE ACTION at 4 (24 April 2002). While the Examiner's assertion might be correct, it is both illegal and immaterial.

The assertion is illegal, because judicial notice cannot be used to establish what a skilled artisan would envisage. The facts concerning the state of the art may be subject to disagreement and are thus "not amenable to the taking of [judicial] notice." In re Eynde, 178 USPQ 470, 474 (C.C.P.A. 1973) ("The facts concerning the state of the art are normally subject to the possibility of rational disagreement among reasonable men and **are not amenable to the taking of [judicial] notice**. If evidence of the knowledge possessed by those skilled in the art is to be properly considered, it must be timely injected into the proceedings"). If evidence regarding skill in the art is to be considered, it must be provided by a reference. Id.; accord, Ex parte

Grochowski, No. 95-1343 at 5 (B.P.A.I. June 27, 1995) (suggestion to combine cannot be based on a judicially-noticed fact). Thus, "Assertions of technical facts in areas of esoteric technology **must always be supported** by citation to some reference work recognized as standard in the pertinent art. ... Allegations concerning specific 'knowledge' of the prior art ... should also be supported. ... The facts so noticed . . . **should not** comprise the principle evidence upon which rejection is based." In re Ahlert, 165 USPQ 418, 420 (C.C.P.A. 1970). Because of this, relying on judicial notice of what a skilled artisan would envision, is reversible error. Ex parte Nouel, 158 USPQ 237 (B.P.A.I. 1967).

Here, the Applicant asked the examiner to provide an AFFIDAVIT OF REFERENCES showing art teaching penetration to the depth of hair bulbs. REPLY at 9 (8 Feb. 2001). The examiner refused. Because the Examiner refused this request, she cannot rely on her judicially-noticed fact. The rejection must accordingly be withdrawn.

4. The Judicially Noticed fact is non-enabling

Assuming the Examiner had provided an Affidavit of References as she was legally required to do, the rejection should nonetheless be withdrawn. This is because even if the Examiner's factual assertion regarding what one of skill in the art would "envision" were true[6], Roentsch still does not teach enough to enable such a visionary to practice the claim limitation, "*a depth of approximately the depth of hair bulbs.*" Knowles, W.R., DECLARATION at ¶¶ 36-45 (24 June 2002). The Examiner does not dispute this. *See* OFFICE ACTION at 4 (24 April 2002). The examiner does not even allege that Roentsch enables this limitation. *Id.* The judicially-noticed level of skill and vision in the art is an "invitation to experiment," not an enabling disclosure. Because it is undisputed that Roentsch does not enable one of skill in the art to practice the claimed invention, the rejection must be withdrawn as a matter of law. Biogen Inc. v. Amgen Inc., __ F.3d __, __ (D.Mass. 1999).

[6] "One of skilled artisan would have envisaged the enhanced delivery of active compound to the hair bulbs . . . via improved penetration thru skin layers by penetration enhancer."

5. The examiner is collaterally estopped from arguing that the reference teaches "penetrating the skin surface to a depth of approximately the depth of hair bulbs

The examiner has acknowledged the references relied on in the first four OFFICE ACTIONS do not enable the claim limitation "*a depth of approximately the depth of hair bulbs.*" The examiner has thus conceded that such references cannot anticipate the claims. *See* OFFICE ACTION at ¶ 1 (24 April 2002) (withdrawing rejections over Hoke, Orentreich, Bradbury, Bazzano, Rajadhyaksha).

Now, the examiner cites new art. The examiner acknowledges these new references do not disclose the claim limitation "*penetrating the skin surface to a depth of approximately the depth of hair bulbs.*" The examiner argues, however, that such references nonetheless anticipate the claims.

The examiner is prohibited from doing so, as a matter of law. This is because the examiner is collaterally estopped from arguing that the new references bar the claims.

6. Collateral Estoppel applies to patent office proceedings

Collateral estoppel[7] arises when an *issue of fact* is litigated to a final judgment, and that fact *is essential* to the final judgment. Texas Instr. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1568 (Fed.Cir. 1996). Collateral estoppel applies to Patent Office proceedings. Overland Motor Co. v. Packard Motor Co., 274 U.S. 417, 421 (1927) ("Especially is this principle applicable to the proceedings of the Patent Office, which are so nearly akin to judicial proceedings as to be most appropriately designated as quasi-judicial.").

Collateral estoppel thus prohibits the examiner from re-litigating issues which have already been decided. Further, it prohibits the examiner from re-litigating issues that "*could have been* raised." Allen v. McCurry, 449 U.S. 90, 94 (1980). Thus, in Patent Office proceedings, collateral estoppel is "*an absolute bar* to relitigation, not only of those matters actually litigated in the prior suit, but also any other matter which might have been acted upon in the prior suit." Schwartz, S.D., *Res Judicata As Applied in Patent Office Prosecution...*, 159 J. PAT. OFF. SOC. 637, 638 (1967) (emphasis added). Thus, collateral estoppel applies not only to

[7] Collateral estoppel is also called "issue preclusion." It is a species of "*res judicata.*"

identical factual issues, but also to factual issues which are different, albeit not patentably distinct. In re Lundberg and Zuschlag, 126 USPQ 412 (CCPA 1960) (where the difference between an appealed claim and a previously-adjudicated claim is an obvious modification, collateral estoppel prohibits re-litigating the appealed claim).

7. This factual issue has already been decided

Here, the examiner has already conceded that the art cited in the first four OFFICE ACTIONS do not enable "*a depth of approximately the depth of hair bulbs.*" The examiner has thus conceded this art cannot anticipate the claims. OFFICE ACTION at ¶ 1 (24 April 2002) (withdrawing rejections over Hoke, Orentreich, Bradbury, Bazzano, Rajadhyaksha). The examiner has already conceded this. The examiner is thus prohibited from trying to re-litigate it now. Instead, the examiner has "waived any objection to the application" based on art which does not enable this claim limitation. Overland Motor, 274 U.S. at 421-22. Because the examiner concedes that Roentsch does not enable this, the examiner is collaterally estopped from barring the claims over Roentsch.

Further, the art newly cited "could have been raised" in the prior OFFICE ACTIONS, but the examiner refused to do so. Because these newly-cited art "could have been raised" in a prior office action, the examiner is collaterally estopped from doing so now. Allen v. McCurry, 449 U.S. at 94.

This result is good policy. Forcing Applicant to repeatedly litigate the same factual issue is a "misallocation of resources." Blonder-Tongue, Inc. v. Univ. of Illinois Foundation, 169 USPQ 513, 519 (U.S. 1971). Permitting the examiner to repeatedly dispute the same issue "reflects either the aura of [a] gaming table or 'lack of discipline and of disinterestedness' on the part of the [Patent Office]." *Id.* (noting that collateral estoppel is for "the prevention of harassment" of a party). Here, the spurious rejections raised in the ***five*** Office Actions in this case waste resources and, a cynic might say, even evidence "lack of discipline," "lack of disinterestedness" or even "harassment" by the examiner. The Board should not let the patent examination process degenerate into a "gaming table" of unfounded rejections.

8. Avoiding Collateral Estoppel

The Board may find that collateral estoppel does not apply in this case, for either of two reasons:

The first is if the examiner "wholly failed to grasp the technical subject matter and issues in suit." Blonder-Tongue, Inc., 169 USPQ at 521. If the Board so finds, Applicant respectfully requests the Board expressly explain why.

The second is if the appealed claims are patentably distinct from the originally filed claims. In re Lundberg, 126 USPQ 412, 414 (CCPA 1960) ("Where different inventions are claimed, res judicata does not preclude a new consideration; but where an applicant is merely presenting new claims to the same invention, . . . reconsideration of the issue of patentability is proscribed by the doctrine of res judicata.") (Rich, J.). If the Board finds the appealed claims patentably distinct from the originally filed claims, then Applicant respectfully requests the Board to expressly explain why (the examiner certainly hasn't).

9. Conclusion

Because it is undisputed that Roentsch lacks a claim limitation and does not enable (and in fact actively teaches away from) the claimed invention, the rejection must be withdrawn as a matter of law.

D. Group 4

The Group 4 claims (11, 22) stand rejected as obvious under 35 U.S.C. § 103 in light of Roentsch. This rejection should be reversed because Roentsch does not teach the claim limitation, "*penetrating the skin surface to a depth of approximately the depth of hair bulbs*." *See supra*.

VII. SUMMARY

The Board should Order the examiner collaterally estopped from further contesting the issue of whether the claims can be anticipated by a reference which does not expressly enable "penetration to a depth of approximately the depth of hair bulbs," and Order:

A. Group 1: Affirm the (uncontested) rejection of the claims as anticipated under 35 U.S.C. § 102(b) by Gibson. Reverse the rejection of the Group 1 claims as anticipated under 35 U.S.C. § 102(e) by Roentsch.

B. Group 2: Reverse the § 102(e) and § 103 rejections over Crandall, and allow the claims to issue.

C. Group 3:

a. Reverse the § 102(e) and § 103 rejections over Roentsch;

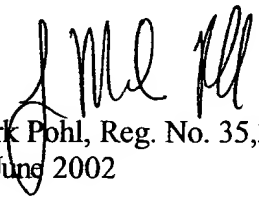
b. require that claims 2 and 13 be rewritten in independent form; and

c. allow the claims to issue.

D. Group 4: Reverse the § 103 rejections over Roentsch, and allow the claims to issue.

The NOTICE OF APPEAL and the REQUEST FOR ORAL HEARING have been previously filed. Please find enclosed (i) copies of the references discussed; (ii) two additional copies of this APPEAL BRIEF; and (iii) a FEE TRANSMITTAL FORM with the required appeal brief fee.

Respectfully submitted,



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VIII. CLAIMS ON APPEAL

1. A composition of matter intended for topical use in preventing or treating alopecia, or maintaining healthy hair, said composition of matter comprising:

a) an active compound selected from the group consisting of: a pharmaceutically or cosmetically effective topical amount of a 5α-reductase inhibitor and minoxidil, and

b) a non-retinoid penetration enhancer, said penetration enhancer present in a concentration sufficient to aid said active compound in penetrating the skin surface to a depth of approximately the depth of hair bulbs.

2. The composition of claim 1, wherein said active compound comprises a 5α-reductase inhibitor.

3. The composition of claim 1, wherein said active compound comprises minoxidil.

4. The composition of claim 3, further comprising a 5α-reductase inhibitor.

5. The composition of claim 4, wherein the ratio of penetration enhancer to 5α-reductase inhibitor to minoxidil in the composition is approximately 0.5 grams : 1 gram.

7. The composition of claim 5, wherein said 5α-reductase inhibitor is present in a concentration of 0.5 grams per 4 ounces of finished liquid.

8. An article of manufacture comprising the composition of claim 4, labeled for topical cosmetic use in maintaining normal, healthy hair.

9. An article of manufacture comprising the composition of claim 4, labeled for topical pharmaceutical use in preventing or treating a disease.

10. The composition of claim 9, wherein said disease comprises alopecia.

11. The composition of claim 4, further comprising a sunscreen in an amount effective to screen radiation.

12. A method for preventing or treating alopecia, or maintaining healthy hair, said method comprising:

a) Topically administering an active compound selected from the group consisting of: a pharmaceutically or cosmetically effective topical amount of a 5α-reductase inhibitor and minoxidil, together with

b) a non-retinoid penetration enhancer, said penetration enhancer present in a concentration sufficient to aid said active compound in penetrating the skin surface to a depth of approximately the depth of hair bulbs.

13. The method of claim 12, wherein said active compound comprises a 5α-reductase inhibitor.

14. The method of claim 12, wherein said active compound comprises minoxidil.

15. The method of claim 14, wherein said active compound further comprises a testosterone blocker.

16. The method of claim 15, wherein the ratio of penetration enhancer to 5α-reductase inhibitor to minoxidil in the composition is approximately 0.5 grams : 1 gram.

18. The method of claim 16, wherein said 5α-reductase inhibitor is present in a concentration of 0.5 grams per 4 ounces of finished liquid.

19. The method of claim 15, labeled for topical cosmetic use in maintaining normal, healthy hair.

20. The method of claim 15, labeled for topical pharmaceutical use in preventing or treating a disease.

21. The method of claim 20, wherein said disease comprises alopecia.

22. The method of claim 15, further comprising a sunscreen in an amount effective to screen radiation.

IX. REFERENCES CITED

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